

Appl. No. : 10/633,726  
Filed : August 4, 2003

### REMARKS

Claim 11 has been amended to clarify what the Applicants consider as their invention. This amendment does not narrow the scope of the claim. New Claim 14 has been added. Claims 10-14 remain pending in the application. The Applicants have carefully considered all of the Examiner's rejections and remarks but respectfully submit that the claims are allowable for at least the following reasons.

#### Double Patenting

The Examiner rejected Claims 10-13 for obviousness-type double patenting over U.S. Patent No. 6,626,855. The Applicants are filing with this response a Terminal Disclaimer that disclaims the terminal portion of any patent issuing from the instant application extending beyond the expiration of U.S. Patent No. 6,626,855. Accordingly, the Applicants submit that they have overcome the double patenting rejections.

#### Rejections under § 102

The Examiner rejected Claim 10 under 35 U.S.C. § 102(e) as being anticipated by Vaezy et al. (U.S. Patent No. 6,425,867). The Examiner alleged that Vaezy disclosed the limitations of Claim 10, pointing to column 16, lines 19-26, which refer to applying HIFU therapy to a uterine fibroid, and column 16, lines 50-58, which refer to causing lesions of the blood vessels supplying oxygen and nutrients to the tumor. U.S. Patent No. 6,425,867 was filed on September 17, 1999 and claimed priority to U.S. Provisional Application No. 60/100,812, filed on September 18, 1998. However, the portions of the '867 patent referred to by the Examiner were not present in U.S. Provisional Application No. 60/100,812. Instead, the provisional application merely refers generally to applying HIFU to tumors (U.S. Provisional Application No. 60/100,812 is attached as Exhibit A). The provisional application does not refer to selecting tissue treatment sites so as to cause necrosis that will decrease blood supply to a uterine fibroid. Accordingly, the effective date for the alleged anticipating disclosure is the filing date of the '867 Patent, September 17, 1999.

The Applicants are submitting with this response a declaration under 37 C.F.R. § 1.131 by Lee Weng, one of the inventors of the instant invention. In the declaration, Lee Weng states and demonstrates that the invention claimed in Claim 10 was conceived prior to September 17, 1999 and was diligently pursued until the filing of the provisional application to which the

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instant application claims priority on November 26, 1999. Accordingly, the Applicants respectfully submit that Vaezy is not prior art under § 102(e) because the claimed invention was invented prior to the filing date of September 17, 1999.

Rejections under § 103

The Examiner rejected Claims 11 and 13 under 35 U.S.C. § 103(a) as being obvious over Vaezy in view of Chapelon et al. (U.S. Patent No. 5,601,526) and Claim 12 as being obvious over Vaezy in view of Chapelon and Ribault et al. (U.S. Patent No. 6,488,639). A *prima facie* case of obviousness requires that all of the claim limitations are taught or suggested by the prior art. See M.P.E.P. § 2143.03. Claims 11-14 require energizing an ultrasound transducer to cause pre-focal heating and necrosis. The Examiner alleged that Vaezy teaches use of HIFU therapy and determining a tissue treatment zone and that Chapelon teaches pre-focal heating. The Applicants respectfully disagrees. Chapelon teaches applying ultrasonic waves of two types, thermal waves and cavitation waves. See Chapelon, column 7, lines 35-42. The thermal waves allow for "pre-heating of the tissue of the focal region F." Chapelon, column 7, line 49 and Figure 3. This focal region is the same focal region to which the cavitation waves are applied. Accordingly, the pre-heating taught by Chapelon is only in the focal region. In contrast, Claims 11-14 require "pre-focal heating" (compare Figure 3 of Chapelon with Figure 2B of the instant application). Accordingly, the Applicants respectfully submit that the combination of Vaezy and Chapelon does not teach or suggest all of the limitations of Claim 11 and that therefore, a *prima facie* case of obviousness has not been made with respect to Claims 11-14.

It is worth noting the different goals of Chapelon as compared with the instant application. Chapelon seeks to create "a lesion in tissue to be treated which is strictly limited to the focal point of the treatment device." Chapelon, column 1, line 67 to column 2, line 1. Specifically, Chapelon seeks to "limit[] or avoid[] effects due to heat spreading around the focus point." Chapelon, column 2, lines 2-4. In contrast, the instant specification discloses in one example applying ultrasound such that a "lesion is started at the focus" and then grows "along the central axis of the transducer and towards the transducer to form an elongate lesion" and finally grows "laterally wider." Specification, page 10, lines 5-11.

In addition, as discussed above, the attached declaration of Lee Weng establishes that the claimed invention was invented prior to September 17, 1999. Accordingly, Vaezy is not prior art

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with respect to the additional limitation in Claim 14 of causing a decrease in the blood supply to a tumor at the tissue treatment site. For this additional reason, Claim 14 is allowable over Vaezy in view of Chapelon.

### CONCLUSION


The Applicants respectfully submit that, based on the foregoing amendments and remarks, they have overcome the Examiner's rejections and request a timely issuance of a Notice of Allowance.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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